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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/986,509

11/09/2001

Graham E. Kelly

700136.405C1

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7590

05/25/2010

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

05/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/986,509	Applicant(s) KELLY, GRAHAM E.	
	Examiner John Pak	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-73 and 75-86 is/are pending in the application.
- 4a) Of the above claim(s) 33-72 and 81-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73 and 75-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-32 and 74 have been canceled. Claims 33-73 and 75-86 are pending. Claims 33-72 and 81-86 remain withdrawn from further consideration as being directed to non-elected subject matter. Claims 73 and 75-80 will presently be examined.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/23069.

WO 93/23069 discloses a health supplement comprising a health supplementary amount of naturally occurring phytoestrogens selected from two or more of genistein, daidzein, biochanin A, formononetin, and/or their glycosides (claim 1). Further incorporation of dietary suitable excipient, diluent, carrier or food is disclosed (claim 2). Variety of health benefits are disclosed (page 8, last full paragraph). Foods such as soya that are high in phytoestrogens are associated with an alleviation of menopausal symptoms and hypocholesterolemic effects in humans (page 7, first full paragraph; page 17, first full paragraph). The product of the invention of WO 93/23069 is disclosed to modify or produce "reduced risk of development of many untoward symptoms (including dry vagina, peripheral flushing, depression etc) commonly associated in women with menopause" (see the paragraph bridging pages 15-16).

Because the methyl forms (biochanin A and formononetin) ultimately are largely demethylated to genistein and daidzein, with improved biological efficacy, "it is unimportant whether the isoflavones are present in the claimed product in the methylated or demethylated forms" (page 10, lines 3-6). Leguminous plants such as soyabean are used as sources of phytoestrogens (paragraph bridging pages 10-11 & paragraph bridging pages 12-13). The hypocotyl of soya can be used as a source of phytoestrogens in order to reduce waste products, and the hypocotyl of soya contains 95% daidzein and 5% genistein, which can be used separately (page 12, line 16 to page 13, line 2; see Example 2 on pages 18-19 & Example 4 on page 20; claims 1, 4-5). Further, it is disclosed that "any source rich in phyto-oestrogens may be used instead, if desired" (page 9, line 1).

WO 93/23069 does not expressly disclose formononetin and biochanin A in a single specific exemplified combination. It goes without saying that 90% or more formononetin + biochanin A + any other isoflavone amount feature is also not expressly disclosed.

However, the teachings of WO 93/23069 are not so limited. The key teaching relevant to the instant application claims is that WO 93/23069 discloses the (1) the use of phytoestrogens from the hypocotyl of soya, which contains 95% daidzein and 5% genistein, and (2) equivalence and substitution of isoflavones in their methylated or demethylated forms. Because daidzein and genistein are both demethylated forms (see page 9, chemical formulas), use of their methylated forms, i.e. formononetin and

biochanin A, respectively, would have been obvious and suggested to the ordinary skilled artisan. WO 93/23069 teaches any source rich in phytoestrogens may be used and suggests the specific ratio of 95% formononetin and 5% biochanin A.

Various dependent claims recite or read on "if present" clause. Such a clause does not require anything. The claims have been so interpreted.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Applicant's arguments of 2/8/2010 have been given due consideration but they were deemed unpersuasive.

Applicant argues that WO 93/23069 does not provide a reason to alter any of its composition in the manner of the instant claims. The Examiner cannot agree with applicant's premise. WO 93/23069 actually claims "two or more of ... biochanin A, formononetin, and/or their glycosides" (claim 1). There is no altering when the cited prior art specifically claims the combination. The percentages and proportions of daidzein and genistein are suggestive of percentages and proportions of their methylated forms, formononetin and biochanin A.

Similarly, applicant argues that WO 93/23069 teaches away from the claimed invention, but again, applicant is arguing that the cited reference is teaching away from what it claims in claim 1. This cannot be accepted as a persuasive argument.

Applicant points to Example 4 of WO 93/23069 to argue that the use of soya hypocotyl powder (containing 95% daidzein and 5% genistein) is for treating menstruating or pre-menopausal women, whereas the instant claims relate to treating menopausal symptoms in post-menopausal women or women experiencing different physiological state than in WO 93/23069. Applicant is reminded that the elected invention under examination here is the composition invention, not the method invention. It is not required for a proper prima facie case of obviousness that the prior art composition, which is suggestive of the same composition, is taught for the same exact purpose. In re Kemps, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996). **Moreover**, applicant greatly exaggerates the disclosure concerning menstruating woman in WO 93/23069, which shows 1 woman out of 8 women to be menstruating. This does not mean that the composition of WO 93/23069 is only for menstruating women. Indeed, applicant ignores more explicit disclosure – the product of the invention of WO 93/23069 is disclosed to modify or produce "reduced risk of development of many untoward symptoms (including dry vagina, peripheral flushing, depression etc) commonly associated in women with menopause" (see the paragraph bridging pages 15-16).

In sum, the prior art specifically claims the combination of formononetin and biochanin A, the prior art specifically discloses applicant's intended use, and the prior art disclosure of 95% daidzein mixed with 5% genistein is fairly suggestive of 95% formononetin and 5% biochanin A due to their disclosed equivalence. For all of these reasons and for the reasons of record, applicant's arguments are not found persuasive.

Further, applicant has advanced no objective evidence of nonobviousness for the combination of formononetin and biochanin A, as claimed. Therefore, the outstanding ground of rejection must be maintained.

Claims of copending 10/611,087 were reviewed for potential double patenting issues. At this time, no further action is deemed necessary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616